

REMARKS

Claims 1, 3, 4, 10-16, 18-20, 25-28 and 30-38 are pending in the present application. Claim 29 was previously canceled. Claims 2, 5-9, 17 and 21-24 are newly canceled without prejudice. Claims 4, 20 and 32-38 have been withdrawn from consideration as being drawn to nonelected subject matter.

Claim 1 has been amended to recite a more limited scope of the genus of formula I. The dependency of claims 10 and 28 have been amended so to not depend from a canceled claim. Claims 25-27 and 34-37 have been amended for clarity.

No new matter has been added.

Objection to the Specification

The specification has been objected to because it appeared to contain misplaced paragraphs. Page 22 has been corrected herein. Reconsideration and withdrawal of this objection are respectfully requested.

Claim Objections

Claims 1, 2 and 24 have been objected to because they do not end in periods. Claim 27 has been objected to because of missing commas. Appropriate amendments to claims 1 and 27 have been made herein. Claims 2 and 24 have been canceled without prejudice. Reconsideration and withdrawal of these objections are respectfully requested.

Rejections Under 35 USC § 112, 2nd Paragraph

Claims 1-3, 5-19, 21-26, 28 and 30-31 are rejected under 35 USC §112, second paragraph as being indefinite. Applicants respectfully traverse.

The Examiner objects to certain radicals of R2, R3 and R4 which recite that the alkyl group can contain 0 carbon atoms, e.g., "C₀₋₄alkyl(S)C₀₋₄alkyl."

In response, the Examiner will note that the radicals of R4 no longer recite "C₀" radicals.

With respect to the radicals of R2 and R3, the skilled artisan would readily understand that the scope of the claims does not encompass compounds having an improper valence.

Reconsideration and withdrawal of this rejection are respectfully requested.

Rejections Under 35 USC § 112, First Paragraph

Claims 1-3, 5-19, 21-28 and 30-31 are rejected under 35 USC § 112, first paragraph, as being non-enabling, as set forth on pages 5-19. Applicants respectfully traverse.

Beginning at page 5 of the Office Action, the Examiner asserts that the specification does not enable the invention when the compound is a non-pharmaceutically acceptable salt. Also, beginning at page 10 of the Office Action, the Examiner asserts that the specification does not enable the invention when the compound is a hydrate.

In view of the deletion of the non-pharmaceutically acceptable salts and the hydrates from the claims, this aspect of the rejection are rendered moot.

Beginning at page 14 of the Office Action, the Examiner asserts that the specification does not provide enablement for:

- (1) a pharmaceutical composition comprising a preventatively effective amount of a compound of formula I,
- (2) a compound of formula I for use in therapy, or
- (3) a compound of formula I for use in the treatment or prevention of mGluR 5 mediated disorders.

Applicants respectfully disagree with the Examiner's findings of nonenablement.

First, Applicants respectfully submit that the Examiner has made assertions against the validity of the statements made in the present specification without sufficient supporting evidence. As stated by the Federal Circuit in *In re Oetiker*, 24 USPQ2d 1443 (Fed. Cir. 1992), "[i]f the examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent." (*Id.*, 24 USPQ2d at 1444).

Accordingly, the Examiner has the burden of showing that the application is nonenabling (i.e., that it does not sufficiently teach how to make and use the invention). MPEP § 2164.04 instructs that a specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. As stated by the Federal Circuit:

When rejecting a claim under the enablement requirement of Section 112, the [Patent Office] bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by the claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. *In re Wright*, 999 F.2d 1557, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993).

Upon review of the Examiner's comments in the outstanding Office Action, Applicants respectfully submit that the Examiner has not provided sufficient reasons for doubting that there is sufficient enablement for the present invention as claimed.

The analysis under 35 USC 112, first paragraph is set forth at MPEP §2164.01(a). This section lists many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure satisfies/does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicants are in agreement with the Examiner that there would be some experimentation needed to practice the invention as claimed. However, according to MPEP 2164.01, “[t]he fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation... The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue.” When considering factors (A)-(H), Applicants find that the burden would not be undue. As such, the present invention meets the enablement requirement of 35 USC 112, first paragraph.

Reconsideration and withdrawal of this rejection are respectfully requested.

Rejections Under 35 USC § 102

Claims 1, 3, 5, 9, 10-13, 17-19, 21, 22, 26, 28 and 30 stand rejected under 35 USC § 102(e) as being anticipated by Nowak et al. (U.S. Patent 7,579,349). Applicants respectfully traverse.

Applicants respectfully submit that in view of the above-amendment, the compounds identified by the Examiner have been removed from claim 1. As such, this rejection is rendered **moot.**

Reconsideration and withdrawal of this rejection is respectfully requested.

Application No.: 10/588,754

Docket No.: 5999-0525PUS3


Art Unit 1626

Reply to Non-Final Office Action

Conclusion

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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